

## **REMARKS**

By way of summary, Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 were previously pending in the above-identified application. Claims 25, 47, 60, 72 and 87 have been amended. Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 remain as previously presented. Accordingly, Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 are presented for further consideration.

**A. Response to Rejections of Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 under 35 U.S.C. § 112**

The Office Action rejected Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants have made amendments to Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 to address the Examiner's concerns. Accordingly, Applicants request that the rejections of these claims be withdrawn.

**B. Response to Rejections of Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 under 35 U.S.C. § 103**

The Office Action rejected Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 under 35 U.S.C. § 103(a). Claims 25, 27, 28, 60, 62, 63 and 83-89 were rejected as obvious over U.S. Pub. No. 2001/0012950 by Nishtala et al. ("Nishtala") in view of U.S. Pat. No. 4,738,666 to Fuqua ("Fuqua") and U.S. Pat. No. 6,808,520 to Fourkas et al. ("Fourkas"). Claims 47, 49, 50, 72, 74 and 75 were rejected as being unpatentable over Nishtala in view of Fuqua, Fourkas and U.S. Pat. No. 5,810,776 to Bacich et al. ("Bacich"). Applicants respectfully disagree and traverse these rejections, the characterization of the pending claims, and each and every implicit and explicit official notice.

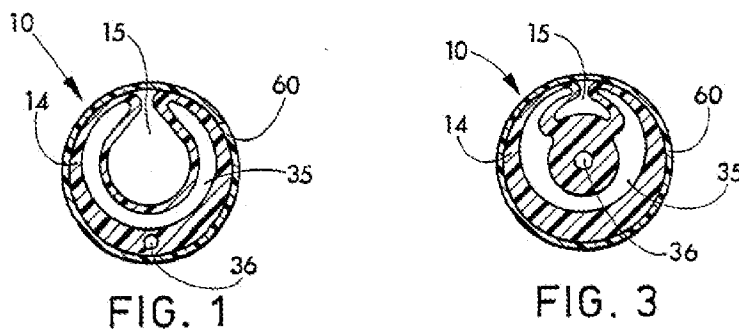
**1. Independent Claim 25**

Claim 25 recites, and Nishtala, either alone or in combination with Fuqua and Fourkas, fails to disclose, *inter alia*, "a circumferentially continuous elongate tubular structure," "a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile," and "inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said

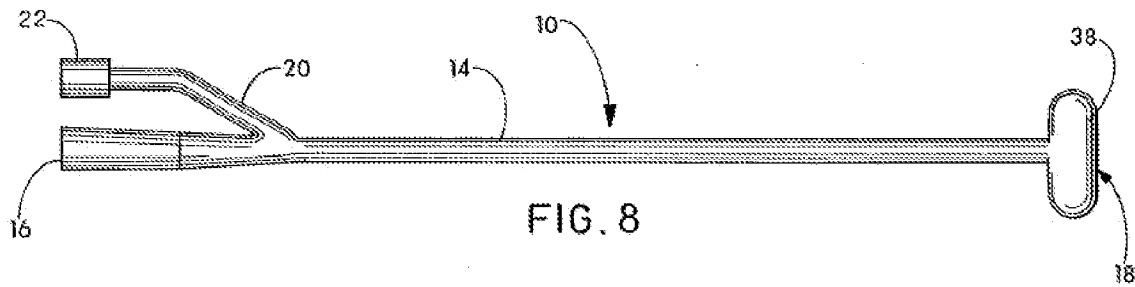
distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.”

The Office Action acknowledged that Nishtala fails to disclose “the distal region having a first, folded, smaller cross-sectional profile,” and relied on Fuqua and Fourkas to disclose this feature. However, Fuqua is directed to a catheter which “expand[s] to full size as a result of the memory of the system.” Fuqua Spec., col. 5, lns. 26-27. Therefore, a person having ordinary skill in the art at the time of invention would not have been motivated to combine the catheter of Fuqua with a balloon such that “inflating a balloon that is positioned within an interior lumen of said distal region of said elongate tubular structure [] expand[s] and unfold[s] said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.”

The Office Action stated that Fuqua discloses “inflating a balloon (36) that is positioned with an interior lumen (35) of the folded distal region of the tubular structure (fig. 3).” Office Action, p. 11. However, item 35, as shown in Fuqua, Fig. 3, reproduced below, is described as a “drainage lumen,” and item 36 is described as an “inflation lumen,” which is “housed within the section of the catheter wall creating the fold.” Fuqua Spec., col. 4, lns. 46-54. Thus, Fuqua fails to disclose that a balloon is or could be positioned within the drainage lumen.



Rather, Fuqua discloses that a “diaphragm or balloon 38, shown in Fig. 8,” reproduced below, is located on the distal end 18 of the catheter 10, and is inflated by the inflation lumen 36. Fuqua, col. 4, lns. 54-56. Accordingly, the balloon 38 is *not* positioned *within* the interior lumen 35.



Nor does the “diaphragm or balloon” of Fuqua “expand and unfold [the] distal region” of Fuqua’s Variable Diameter Catheter. At most, Fuqua discloses that the balloon “will initiate a tear in sheath 60 at the perforations thus facilitating removal of the sheath from the [Variable Diameter Catheter].” Fuqua Spec., col. 5, ln. 67 – col. 6, ln. 2 (emphasis added). The Office Action has interpreted the sheath (60) of Fuqua as the “constraining tubular jacket” of Claim 25, which is distinct from the “elongate tubular structure” of Claim 25. Fuqua does not disclose that its Variable Diameter Catheter, which the Office Action interpreted as the “elongate tubular structure” of Claim 25, is expanded by the balloon. In fact, it is unclear how the balloon of Fuqua could expand the Variable Diameter Catheter, since the balloon is located distally to the Variable Diameter Catheter, as shown in Fig. 8. Accordingly, Fuqua does not disclose that the “elongate tubular structure” is expanded by the balloon.

In addition, even assuming, *arguendo*, that one of skill in the art might add a second balloon to the device of Fuqua, it would not be obvious to place that balloon within the interior lumen of the plastic tube (14). Expansion in Fuqua is accomplished by removing a sheath from the catheter, thereby allowing the catheter to expand as a result of its memory. Fuqua Spec., col. 5, lines 23-27. Thus, even assuming, *arguendo*, that a motivation does exist to combine Fuqua with a balloon, the motivation would be to “cause[] the sheath [60] to separate at the perforations.” Fuqua Spec., col. 5, lines 41-41. Accordingly, one of skill in the art, motivated, *arguendo*, to add a second balloon to Fuqua in a different place than balloon (38), would place the balloon within the fold 15 and not within the interior lumen (35) of the tube (14).

The Office Action further acknowledged that Nishtala fails to disclose “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile,” but relied on Fourkas to disclose this feature. However, Nishtala is directed to a “single integrated device that can reach any of a plurality of expanded diameters upon actuation by a user of an actuating mechanism which directs and controls the dilation of a

dilating element.” Nishtala Abstract. Nishtala further describes the objective of its device as “dial-a-size functionality integrated into a single device.” Nishtala Spec. ¶ [0010]. It is unclear and non-obvious how this “dial-a-size” function could be used in conjunction with a “circumferentially continuous,” folded sheath. For instance, it is unclear how to dial a fold to a plurality of diameters in a controlled manner, since, for example, it would be necessary to precisely control the distance of each crease of the fold from the center of the device. Accordingly, even assuming, *arguendo*, that Fourkas and/or Fuqua disclose a folded sheath, the proposed combination of Nishtala and Fourkas and/or Fuqua would require undue experimentation or “render Nishtala “unsatisfactory for its intended purpose.” M.P.E.P. § 2143.01(V).

For at least the reasons expressed above, Applicants respectfully request that the rejection of Claim 25 be withdrawn and that this claim be passed to allowance.

**2. Independent Claim 47**

Claim 47 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua, Fourkas, and Bacich, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and a beveled distal tip,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.”

Furthermore, Nishtala, either alone or in combination with Fuqua, Fourkas, and Bacich, fails to disclose “the distal region having...a beveled distal tip.” While the Office Action presumably interprets the guide channel 120 of Bacich as the “elongate tubular body” of Claim 47, it is unclear whether the Office Action is interpreting element 108 or element 126 of Bacich (shown together in Bacich Fig. 2) as disclosing the beveled distal tip of Claim 1.

If the Office Action interprets element 108 as the beveled distal tip, Bacich does not disclose guide channel 120 as having element 108. Rather, as demonstrated in Bacich Figs. 3-4 and 11, the guide channel 120 is constructed of a membrane 140 proximal to and distinct from element 108 and which itself does not have a beveled distal tip.

On the other hand, if the Office Action interprets element 126 as the beveled distal tip, Applicants point out that element 126 represents the beveled distal tip of dilator 114, not the guide channel 120. As shown in Fig. 2, the guide channel 120 may take the shape of the dilator 114; however, the guide channel itself is not disclosed as having a “beveled distal tip comprising a leading edge, a trailing edge, and an aperture.”

For at least the reasons expressed above, Applicants respectfully request that the rejection of Claim 47 be withdrawn and that this claim be passed to allowance.

**3. Independent Claim 60**

Claim 60 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua and Fourkas, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 60 be withdrawn and that this claim be passed to allowance.

**4. Independent Claim 72**

Claim 72 recites and, for at least similar reasons as expressed above in relation to Claims 25 and 47, Nishtala, either alone or in combination with Fuqua, Fourkas, and Bacich, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and a beveled distal tip,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 72 be withdrawn and that this claim be passed to allowance.

**5. Independent Claim 87**

Claim 87 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua and Fourkas, fails to disclose, *inter alia*,

“a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, substantially continuous, smaller cross-sectional profile” and “inflating a balloon positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, folded, substantially continuous, smaller cross-sectional profile to said second, unfolded, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 87 be withdrawn and that this claim be passed to allowance.

**6. Dependent Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89**

Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 each depend directly from one of independent Claims 25, 47, 60, 72 and 87. They are each believed to be patentably distinguished, *inter alia*, for the reasons set forth above in relation to the independent claim from which each depends and for the additional features recited therein. Accordingly, Applicants respectfully request that the rejections of Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 be withdrawn and that these claims be passed to allowance.

**C. No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

**Application No.:** 10/728,728  
**Filing Date:** December 5, 2003

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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